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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,293	05/17/2001	Ofer Lider	LIDERI	4984
1444	7590	06/30/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/763,293

**Applicant(s)**

LIDER ET AL.

**Examiner**

Fozia M Hamud

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-10, 14, 18-21 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-10, 14, 18-21 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

1b. Applicants submission filed on 14 April 2004 has been entered. Claims 1-3, 11-13, 15-17 and 22-24 have been cancelled. Claims 4-10 and 18 have been amended and new claims 25-27 have been added. Thus claims 4-10, 14, 18-21, 25-27 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants' amendment filed on 14 April 2004:

(i) The rejection of claims 3-4, 11, 12, 14, 18-21 made under 35 U.S.C. 112, first for not enabling "all" possible IL-2 derived synthetic peptides is withdrawn.

(II) The rejection of claim 7 made under 35 U.S.C. 112, second is withdrawn.

Non-elected Species:

3. Non-elected peptides pep1 and pep3 (SEQ ID NO:2) are rejoined, therefore, all of the pending claims will be searched and examined.

#### ***Claim rejections-35 USC § 112:***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4a. Claims 4-10, 14, 18-21, 25-27 are rejected under 35 U.S.C. 112, first paragraph, while being enabling for a method for the treatment of chronic inflammatory disorder, said method comprising administering to a subject the synthetic peptide of claim 4, does not reasonably provide enablement for a method for the treatment of "acute" inflammatory disorder, said method comprising administering to a subject the synthetic peptide of claim 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 18 and 21 are drawn to a method of treating both acute and chronic inflammation using the peptides of the instant invention, however, the specification does not demonstrate that the peptides of the instant have been administered to treat acute inflammation. Prior art recognizes that IL-2 plays a role in chronic inflammation, (see Feghali et al, page 18, second to last paragraph on column 2 and the bridge between pages 19 and 20). Therefore, the peptides of the instant invention would be expected to be effective against chronic inflammation but not against acute inflammation. The specification does not demonstrate that the peptides of the instant invention are actually effective against acute inflammation. Stedman's Medical Dictionary describes "acute inflammation" as a condition that has a fairly rapid onset, quickly becomes severe, and is usually manifested for only a few days, but which may persist for even a few weeks; characterized histologically by edema, hyperemia, and infiltrates of polymorphonuclear leukocytes. Chronic inflammation is

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characterized by the development of specific humoral and cellular immune responses to the pathogens present at the site of tissue injury. It is well recognized in the art that IL-2 plays a critical role in regulating both humoral and cellular immune responses. Therefore, while the anti-inflammatory peptides of the instant invention are expected to be effective against chronic inflammation, there is no expectation that they would also be effective against acute inflammation.

PM 6/28/04 Regarding claim 4, the instant specification does not enable "a multimer" which consists <sup>of a plurality</sup> ~~polarity~~ of the same or different (i) to (viii). The specification demonstrates that the synthetic peptides of the instant invention and certain variations of them have anti-inflammatory activities. However, the specification does not demonstrate that multimers of said peptides consisting of same or different peptides also have anti inflammatory activities.

Accordingly, in light of the nature of the invention, the state of the art, the high level of unpredictability in the art, the lack of direction or working examples in the specification, and the high quantity of experimentation that would be required to practice the claimed invention, it is concluded that undue experimentation would be required to use the instantly claimed invention.

Claims 5-10, 14, 19 and 25-27 are rejected under 35 U.S.C. 112, <sup>first</sup> ~~second~~ paragraph, in so far as <sup>they</sup> ~~it~~ depends on claim 4 for the limitations set forth directly above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-10, 14, 18-21 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 4 sub-part (i) recites "...peptides pep1, pep2, and pep3 of the sequences...", which renders the claim unclear. It is unclear whether the claimed peptides "consist" or "comprise" the recited sequences. It is suggested to use the conventional language of "consisting of" ~~or "comprising of"~~ to overcome this rejection.

5b. Claims 4, 5, 7, 9, 14, 25, 26 and 27 are vague and indefinite for reciting "..... derivatives thereof", because the metes and bounds of the claims cannot be ascertained. Appropriate correction is required.

5c. Claim 4 in sub part (vi) recites "chemical derivatives are derivatives in which additional chemical moieties not normally part of the peptides are present;....", which renders the claim indefinite, because it is unclear which additional chemical moieties should the claimed peptides comprise? The metes and bounds of the claim cannot be ascertained.

5d. Claim 4 also recites "...cyclic derivatives of peptides...", in sub-part (vii), which renders the claim vague, because it is unclear which cyclic derivatives are encompassed by the claim or how these cyclic derivatives are derived?

5e. Claim 4 sub-part (i) recites "...peptides pep1, pep2, and pep3 of the sequences...", which renders the claim unclear. It is suggested to use the conventional language of "consisting of" to overcome this rejection.

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5f. Regarding claim 4 (ix), it is unclear what "different" peptides are encompassed by the claim. *The metes & bounds of the term "different" are unclear*

**Conclusion :**

3. No claim is allowed.

**Advisory Information:**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
22 June 2004

*Prema Mertz*  
**PREMA MERTZ**  
**PRIMARY EXAMINER**